

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA  
MDL No. 15-2666 (JNE/FLN)**

In re: BAIR HUGGER FORCED AIR  
WARMING DEVICES PRODUCTS  
LIABILITY LITIGATION

**MEMORANDUM IN  
SUPPORT OF MOTION TO  
QUASH SUBPOENAS AND  
IN RESPONSE TO MOTION  
TO COMPEL**

This Document Relates To:  
*Nugier*, 16-cv-4246

The United States of America, by and through its attorneys, Gregory G. Brooker, Acting United States Attorney for the District of Minnesota, and David W. Fuller, Assistant United States Attorney, pursuant to 38 C.F.R. §§ 14.800 *et seq.*, hereby submits this memorandum (a) in support of its motion to quash Defendants’ Rule 45 subpoenas served on Dr. Henry Bernstein and Dr. Paola Lichtenberger, and Defendants’ Rule 30(b)(6) subpoena directed to the Miami VA Medical Center; and (b) in response to Defendants’ motion to compel.

**BACKGROUND**

**I. Overview of Applicable Law**

“It is long settled law that, as an attribute of sovereign immunity, the United States and its agencies may not be subject to judicial proceedings unless there has been an express waiver of that immunity.” *EPA v. General Electric Co.*, 197 F.3d 592, 597 (2d Cir. 1999) (citations omitted). “A judicial proceeding is considered brought against the sovereign if the result could serve ‘to restrain the Government from acting, or to compel it to act.’” *Id.* (quoting *Dugan v. Rank*, 372 U.S. 609, 620 (1963)). There is no waiver of sovereign

immunity under the discovery rules to compel a non-party federal employee or agency to produce records. *Id.*; *see also Alltel Communications, LLC v. DeJordy*, 675 F.3d 1100, 1103-04 (8th Cir. 2012) (“[Third-party subpoenas] command a government unit to appear in federal court and obey whatever judicial discovery commands may be forthcoming. The potential for severe interference with government functions is apparent.”).

Accordingly, litigants wanting to obtain evidence from the government generally must submit requests pursuant to the Freedom of Information Act (FOIA) or the so-called *Touhy* regulations<sup>1</sup> promulgated by the various federal Departments. Compliance with such regulations is mandatory, and numerous courts have denied motions to compel compliance with a subpoena directed at a federal officer and/or granted the government’s motion to quash where, as here, the government is not a party to the proceeding, and the agency denied the request under its *Touhy* regulations. *See, e.g., Moore v. Armour Pharmaceutical Co.*, 927 F.2d 1194, 1197-98 (11th Cir. 1991) (affirming district court’s decision to quash subpoena for testimony by federal employees where request was denied by the agency); *Boron Oil Co. v. Downie*, 873 F.2d 67, 73 (4th Cir. 1989) (holding EPA had not waived sovereign immunity, quashing subpoena of EPA employee served in state proceeding where EPA had instructed the employee not to testify); *Saunders v. Great Western Sugar Co.*, 396 F.2d 794, 795 (10th Cir. 1968) (vacating district court order demanding compliance with subpoena duces tecum directed at federal officials where the agency had determined the documents were privileged); *Reifsteck v. Paco Bldg. Supply*

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<sup>1</sup> After *United States ex rel. Touhy v. Ragen*, 430 U.S. 462 (1951).

*Co.*, 410 F. Supp. 2d 848 (E.D. Mo. 2006) (granting motion to quash subpoena seeking testimony and documents from EEOC mediator after EEOC denied the request). Agency responses to *Touhy* requests are discretionary, and courts may remand such decisions only if found to be “arbitrary and capricious” under the Administrative Procedure Act (APA).<sup>2</sup>

The Department of Veterans Affairs (VA) *Touhy* regulations prohibit agency personnel, even under subpoena, from testifying or producing records without “prior written approval” from the designated responsible VA official. 38 C.F.R. § 14.806. In making such approval decisions, the responsible official must consider, *inter alia*, the list of regulatory factors set forth at 38 C.F.R. § 14.804, the first and foremost of which is “[t]he need to avoid spending the time and money of the United States for private purposes and to conserve the time of VA personnel for conducting their official duties concerning servicing the Nation’s veteran population.” *Id.* subd. (a); *see also* 38 C.F.R. § 14.803 (requiring official to “consider the effect in this case, as well as in future cases generally . . . , which testifying or producing records . . . will have on the ability of the agency or VA personnel to perform their official duties”).

Other considerations include the need to avoid endorsing a litigant’s position or favoring one party over another, 38 C.F.R. § 14.804(i)-(j); the need to avoid violating any

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<sup>2</sup> *See Elnashar v. Speedway SuperAmerica, LLC*, Civil No. 02-4133 (D. Minn. Sept. 7, 2004 (Doc. 84)) (Mayeron, M.J.), p. 15 (“[T]his Court concludes that it must review the agency’s [*Touhy*] decision under the standard set forth by the APA”) (collecting cases); *Geiger v. United States*, 1993 U.S. Dist. LEXIS 5525 (D. Minn. April 7, 1993). While the Eighth Circuit appears not to have squarely addressed the standard of review, the United States submits that the more persuasive authority supports review under the APA standard. *See generally EPA v. General Electric*, 197 F.3d 592 (2d Cir. 1999).

applicable laws (such as confidentiality statutes), *id.* subd. (f), and a general prohibition against VA employees giving expert or opinion testimony, 38 C.F.R. § 14.808. Unless it is not feasible, anyone making a request for documents or testimony to the VA must set forth a summary of its nature and relevance in an affidavit. 38 C.F.R. § 14.805.

## **II. Defendants' Request for Documents and Information**

On August 4, 2017, Scott Provencher, counsel for Defendants 3M Company and Arizant Healthcare Inc., spoke with staff attorney Barbara Kehoe in the pertinent VA District Counsel's office to discuss Defendants' desire to obtain documents and information from the Miami VA Medical Center (VAMC), including deposition testimony from orthopedic specialist Dr. Henry Bernstein and infectious-disease specialist Dr. Paola Lichtenberger. Declaration of Barbara Kehoe (Kehoe Decl.) ¶¶ 4, 16. Ms. Kehoe, who serves as the designated deciding official for these purposes in the region and has handled scores of *Touhy* requests over the years, was immediately struck by the unusual breadth of Defendants' request, in terms of the number of witnesses sought to be deposed, the amount of time sought with each witness, and the number of document categories at issue. *Id.* ¶ 5. In her experience, this request was much broader and more burdensome than most. *Id.*

Ms. Kehoe informed Mr. Provencher of the process for seeking such information and apprised him during the initial conversation that third-party testimony by VA employees is rarely approved. *Id.* ¶¶ 2, 5-6. At this time Ms. Kehoe suggested that Defendants could provide a list of questions for the doctors as an alternative to lengthy live depositions that may require considerable preparation time. *Id.* ¶ 7. Ms. Kehoe also

indicated that a more appropriate way to seek documents would be to submit a FOIA request. *Id.*

Mr. Provencher responded that Defendants strongly preferred in-person deposition testimony. *Id.* ¶ 8. Either at this time or in a subsequent conversation, Mr. Provencher made clear that Defendants anticipated each doctor's deposition would last no less than four hours – and that he could not provide a time estimate for the Rule 30(b)(6) deposition. *Id.*

Also on August 4, Mr. Provencher emailed a letter to Ms. Kehoe explaining this litigation and Defendants' reasons for believing that the documents and information they seek are necessary. Kehoe Decl. ¶ 9. Ms. Kehoe forwarded the request to VA's office of General Counsel (OGC) in Washington, D.C. for review and advisement, given that the request arises in a multidistrict litigation that she believed could impact other VA facilities across the country. *Id.* ¶ 10. Although Ms. Kehoe was out of the office most of the week of August 7-14, she did notice a message from OGC during this time instructing her to delay any response to Defendants' request until OGC could review the matter. *Id.* ¶¶ 11-12.

Ms. Kehoe received Defendants' subpoenas on August 16 and 18, and received follow-up letters from Mr. Provencher on August 21 and 22. Kehoe Decl. ¶¶ 16-17. The Rule 30(b)(6) subpoena directed to the Miami VAMC includes attachments listing 11 deposition topics and categories of documents sought, each containing subparts. Declaration of Benjamin Hulse (Hulse Decl.), Ex. 3 (Doc. 704-3); *see also* Def. Mem. (Doc. 703) pp. 3-5 (summarizing deposition topics). Defendants' follow-up letters set forth

their theories of relevance and indicated “flexibility in the date and start time” of the depositions. Hulse Decl. Ex. 1 (Doc. 704-1), at p. 3; *id.* Ex. 2 (Doc. 704-2) at p. 3; *id.* Ex. 3 (Doc. 704-3) at p. 3. The letters did not indicate any other sort of flexibility. *See id.* Each letter also included a boilerplate paragraph asserting without analysis Defendants’ view that most of the *Touhy* factors were met. *See id.*

### **III. The VA’s Response to Defendants’ Request**

In exercising her discretion to consider Defendants’ requests, Ms. Kehoe was required to take many factors into account. She was aware, for example, that Defendants had not taken her up on the idea of submitting written questions for the doctors in lieu of in-person depositions, and that they evidently had not submitted a FOIA request as she suggested on August 4. Kehoe Decl. ¶ 8. Ms. Kehoe considered, too, the fact that the surgery at issue took place five years ago, making it all the more difficult to track down much of the information and documents sought by Defendants. *Id.* ¶ 21.

Ms. Kehoe also contacted the Miami VAMC Hospital Director, Chief of Staff, Chief of Surgery, Dr. Bernstein, and Dr. Lichtenberger, and received confirmation that both doctors were very busy with veteran care and that scheduling appointments for veterans was a challenge and priority for the facility. *Id.* ¶ 22. From this communication and from her experience working as a VA staff attorney, Ms. Kehoe is aware that taking two providers away from patient care for more than a half-day each would greatly impact the agency’s ability to serve patients, given that VA doctors work in a medical system straining to meet current demands with an already-taxed appointment system. *Id.*

In addition, Ms. Kehoe knew that locating documents and information concerning, for example, the configuration and ventilation of the operating room at the time of Plaintiff's surgery; all persons in attendance at the time; "temperature and humidity logs" for the operating room; and the number of times the operating room door was opened during Plaintiff's surgery (*see* Hulse Decl. Ex. 3 (Doc. 704-3) at pp. 15-16 & 22-23, Topic 7); would require many, many hours of work on the part of numerous VAMC departments, staff members, and even former contractors. Kehoe Decl. ¶ 21. Ms. Kehoe considered, too, the VA *Touhy* regulations' prohibition against providing expert testimony absent "exceptional circumstances," 38 C.F.R. § 14.808(a), observing that much of the testimony Defendants seek falls into that category. *Id.* ¶ 23. Another issue Ms. Kehoe considered in the exercise of her discretion was the statutory prohibition against sharing VA quality assurance records, found at 38 U.S.C. § 5705, and the high likelihood that many documents sought by Defendants would fit that description. *Id.* ¶ 20.

On August 24, 2017, Ms. Kehoe sent a "*Touhy* letter" to Mr. Provencher setting forth the VA's response to Defendants' request. Hulse Decl. Ex. 4 (Doc. 704-4). This letter reiterated Ms. Kehoe's recommendation to request records by means of the FOIA process, and explained several of the agency's reasons for denying Defendants' requests as presented. Some of the listed reasons included the unjustified diversion of VA personnel from their official duties, the burdensomeness of the subpoena demand, the prohibition against providing expert or opinion testimony, and the statute preventing the VA from releasing documents that reflect confidential quality assurance programs. *Id.* For these and other reasons, Ms. Kehoe's letter concluded that "at this time, it is our determination

that the VA employees and records you have subpoenaed are not authorized by this office or required to comply with the demand.” *Id.* at p. 3.

Defendants filed their motion to compel discovery on August 29, 2017.<sup>3</sup>

## ARGUMENT

### **I. Defendants Concede That the “Arbitrary and Capricious” Standard Applies.**

In their heading, Defendants state: “This Court Reviews the Miami VA’s Objections Under an ‘Arbitrary and Capricious’ Standard.” Def. Mem. p. 8. They also note (correctly) that “[s]ome courts” have applied the more liberal discovery provisions from the Federal Rules, and cite the non-binding *Liptak* decision from this district as a supposed example. *Id.* (citing *Liptak v. Ramsey County*, 2016 WL 5662082, at \*8 (D. Minn. Aug. 8, 2016)). *Liptak*, however, ultimately concluded that the requesting party had entirely failed to comply with the agency’s *Touhy* regulations, and instructed the party to do so. *Id.* at \*13. Moreover, quite unlike the VA’s *Touhy* regulations, those of the relevant Department in *Liptak* – Health and Human Services – specifically direct “compl[iance] with the terms of a validly issued subpoena.” *Id.* at \*8. Thus, *Liptak* is unhelpful here; the deferential “arbitrary and capricious” standard of review applies to the question at hand.

### **II. The VA Reasonably Considered the Appropriate Factors.**

Under the APA, agency action may only be set aside if it is found to be “arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law.” 5 U.S.C. §

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<sup>3</sup> The U.S. Attorney’s Office for the District of Minnesota learned of this matter only after the motion to compel was filed.



706(2)(A). The arbitrary and capricious standard “is a narrow one and the court is not permitted to substitute its judgment for that of the agency.” *U. S. v. Massey*, 380 F.3d 437, 440 (8<sup>th</sup> Cir. 2004). As explained below, the VA’s response to Defendants’ discovery requests meets this standard.

#### **A. The Deciding Official Took The Request Seriously.**

As an initial matter, Defendants are wrong to suggest that the VA simply denies any and all requests for documents and information, as if the agency thinks the *Touhy* regulations protect it from ever having to divulge anything. Both Ms. Kehoe’s denial letter and her declaration make clear (especially when viewed together) that she considered the specifics of what Defendants presented to the agency before rendering her decision. For example, prior to issuing the letter, Ms. Kehoe engaged with Defendants’ counsel by phone, encouraging him to submit a FOIA request and to consider posing written questions for the doctors in order to spare them having to sit for depositions predicted to last no less than a half-day each. Kehoe Decl. at ¶ 8. Ms. Kehoe also brought Defendants’ requests to the attention of both the VA’s Office of General Counsel in Washington, D.C. and numerous officials at the Miami VAMC – who specifically confirmed the doctors’ busy schedules – before preparing her response. *Id.* ¶¶ 10, 22. Moreover, she considered the nature and breadth of Defendants’ request, which relates to a surgery from over five years ago and includes an array of different topics and document categories. *Id.* ¶ 21. All this shows that the VA took time to consider the request in a thoughtful manner.

Defendants’ memorandum repeatedly takes the VA to task for issuing a supposedly “boilerplate” denial letter. *See, e.g.*, Def. Mem. (Doc. 703) at pp. 2, 5, 6. The VA letter,

however, contains more than adequate explanation to meet the deferential APA standard – and the declaration of Barbara Kehoe describes in greater detail the considerations that went into the decision, which accord fully with the regulatory scheme. In any case, for Defendants to accuse the VA of employing boilerplate language amounts to the pot calling the kettle black – given the nearly identical conclusory text appearing in each of their request letters, repeatedly asserting without analysis Defendants’ position that the *Touhy* factors are met. *See* Hulse Decl. Ex. 1 (Doc. 704-1), at p. 3; *id.* Ex. 2 (Doc. 704-2) at p. 3; *id.* Ex. 3 (Doc. 704-3) at p. 3.

#### **B. The Deciding Official Applied the Pertinent Regulations.**

An overarching theme of the VA’s *Touhy* regulations is the importance of considering the effect that testifying or producing records will have – in “this case, as well as in future cases generally” – on the “ability of the agency or VA personnel to perform their official duties.” 38 C.F.R. § 14.803 (“Policy”). Ms. Kehoe bore this in mind in deciding that Defendants’ request did not meet the factors set forth at 38 C.F.R. § 14.804. *See* Kehoe Decl. ¶¶ 14, 22; Hulse Decl. Ex. 4 (Doc. 704-4), p. 3; 38 C.F.R. § 14.804(a) (noting the “need to avoid spending the time and money of the United States for private purposes and to conserve the time of VA personnel for conducting their official duties concerning servicing the Nation’s veteran population”); *id.* subd. L (noting the “need to minimize VA’s possible involvement in issues unrelated to its mission”). Given counsel’s stated need for no less than a half day with each doctor (plus prep time), and the extensiveness of the lists of 30(b)(6) deposition topics and document categories – 11 separate points, each containing subsections – Ms. Kehoe reasonably concluded that the

requests did not fit within this paramount regulatory factor. Kehoe Decl. ¶¶ 21-22. In her experience handling scores of *Touhy* requests for the VA over the years, this request was much broader and more burdensome than most, in terms of the number of witnesses sought to be deposed, the time sought with each witness, and the number of document categories at issue. *Id.* ¶ 5. By itself, this would constitute sufficient grounds to deny the request.<sup>4</sup>

Ms. Kehoe also properly reasoned that many other regulatory factors were not met, including the fact that disclosure here is not apparently “necessary to prevent the perpetration of fraud or other injustice,” 38 C.F.R. § 14.804(c), that any disclosure may risk “endorsing or supporting a position advocated by a party to the proceeding,” *id.* subd. (j), and the need to “minimize VA’s possible involvement in issues unrelated to its mission,” *id.* subd. (l). Kehoe Decl. ¶ 24. Moreover, because the bellwether plaintiff here happens to be a veteran, the concern over creating an “appearance of VA or the Federal government favoring one litigant over another,” *id.* subd. (i) is heightened because any perception of favoring Defendants (through negotiation or otherwise) could impact Mr. Nugier’s willingness to accept care from the VA. Kehoe Decl. ¶ 25.

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<sup>4</sup> Defendants’ offer of “flexibility” in scheduling the depositions – including potentially starting after working hours – does not address the VA’s ultimate concern, which relates to the *amount* of time devoted to this non-mission-related activity. As government employees, the deponents would be paid for their time testifying regardless of when it might occur. The main issue, both in this case and considered as a precedent for future situations, is occupying these medical professionals who are also public servants with this distracting activity as part of their official duties. Inescapably, any time they spend on this private litigation is official time they are unable to devote to patient care. *See* Kehoe Decl. ¶ 26.

The August 24 letter also notes that, under 38 C.F.R. § 14.808, VA personnel ordinarily may not provide “expert or opinion testimony concerning official VA subjects.” Hulse Decl. Ex. 4 (Doc. 704-4) p. 3. This general rule may be overcome only in “exceptional circumstances” and where “the anticipated testimony will not be adverse to the interests” of the VA and the United States. 38 C.F.R. § 14.808(a). The prohibition is so serious that, as the *Touhy* regulation makes clear, providing such testimony absent approval may expose VA employees to *criminal liability* as well as disciplinary or other adverse personnel action. 38 C.F.R. § 14.808(b)(iv) (citing 18 U.S.C. §§ 201-209).

The rule against providing expert testimony would make it especially difficult to allow the discovery Defendants seek here. Kehoe Decl. ¶ 23. For example, the main reason they want Dr. Bernstein to testify is that he was the “orthopedic specialist who was the attending physician and surgeon during Plaintiff’s total knee replacement” and two subsequent surgeries in 2012. Hulse Decl. Ex. 1 (Doc. 704-1), p. 2. As such, Defendants understandably wish to learn about Dr. Bernstein’s “role in Mr. Nugier’s surgery, care and treatment, and his experience with the Bair Hugger patient warming system that is that the center of this lawsuit,” *id.*; his “personal knowledge of Plaintiff’s medical history, care and treatment,” *id.*; his “specialized knowledge of the benefits and risks associated with total knee arthroplasty, including the possibility of infection,” *id.* p. 3; and his “experience with the Bair Hugger patient warming system, knowledge of its use during [the] March 7, 2012 surgical procedure, and likely knowledge of its safety and efficacy,” *id.* The problem is that all this at least borders on forbidden expert testimony – some would plainly cross the line – and parsing out what does and does not fit that description during a lengthy

deposition (on pain of criminal sanctions) would be a tall task indeed. Kehoe Decl. ¶ 23. Defendants have made no showing of “exceptional circumstances” that would warrant allowing expert testimony here, and we are aware of no basis for doing so.

Similar considerations apply to Defendants’ desire to depose both Dr. Lichtenberger and the Miami VAMC as an entity – as is clear from a perusal of Defendants’ follow-up letter (Hulse Decl. Ex. 2, Doc. 704-2) and Exhibits A & B to their Rule 30(b)(6) deposition notice (*id.* Ex. 3, Doc. 704-3). It is very hard to see how Defendants could get what they feel they need out of any of the depositions they seek without crossing over into opinion or expert testimony. Kehoe Decl. ¶ 23.

### **C. The Statutory “Quality Assurance Privilege” Applies.**

Likewise, many of the documents Defendants seek cannot be produced according to a statute meant to ensure strict confidentiality of VA records and documents associated with the agency’s medical quality assurance (QA) program. *See* 38 U.S.C. § 5705; Kehoe Decl. ¶ 20. This provision is referenced in the VA *Touhy* regulations at 38 C.F.R. § 14.804(f), and at the end of Ms. Kehoe’s August 24, 2017 letter (Hulse Decl. Ex. 4 (Doc. 704-4), p. 3). In short, to reduce the possibility of harm to patients, VA health care systems are required to have a medical quality-assurance means of identifying causal contributing factors of incidents in order to understand why an adverse event occurred and learn from such events to prevent recurrence on a systemwide basis. Accordingly, the VA employs a nationwide internal and external reporting system for the purpose of learning about risks and hazards that threaten patient safety. The confidentiality of reported information is

crucial to the success of this reporting system, as Congress recognized in creating the confidentiality protections of 38 U.S.C. § 5705.

The statute requires the Secretary for Veteran's Affairs to specify by regulation which activities meet the definition of a VA medical quality assurance program. *See* 38 U.S.C. § 5705(d)(1). Regulations promulgated pursuant to this authority define the protected materials broadly to encompass "continuous or periodic data collection" relating to "either the structure, process, or outcome of health care provided in the VA." 38 C.F.R. § 17.500(c). "Confidential and privileged documents" under VA rules and regulations therefore include, but are not limited to, medical record reviews, surgical case/invasive procedure reviews, infection control review and surveillance, occurrence screening, and tort claims peer reviews. *See generally* 38 C.F.R. § 17.501. Fines of up to \$20,000.00 may be assessed for unauthorized disclosures of some of these materials. *See* 38 C.F.R. § 17.511.

Reviewing Defendants' list of requested documents (Hulse Decl. Ex. 3 at pp. 18-23) makes clear that much of what they seek will very likely run afoul of the Quality Assurance Privilege. For example, Defendants seek:

- documents "regarding the Bair Hugger system and any possible infection risk presented by or associated with the use of the Bair Hugger system or any other forced-air patient warming system," *id.* at p. 21 (Request No. 2);
- "performance logs" relating to "cleaning, disinfection and infection control and prevention measures" and to "equipment servicing, maintenance and cleaning protocols," *id.* at p. 22 (Request Nos. 4-6);

- “information and documentation as to the number of time[s] the operating room door was opened during Mr. Nugier’s surgery,” *id.* at p. 23 (Request No. 7);
- “performance logs” relating to “maintenance and cleaning of the HVAC system” used in the operating room, and “whether conventional or laminar air flow was used during the surgery,” *id.* at pp. 23-24 (Request No. 10).

These and other requests call for the very sort of information that Congress has instructed the VA to maintain as “confidential and privileged” under 38 U.S.C. § 5705. Kehoe Decl. ¶ 20. No statutory exception exists for civil subpoenas, and accordingly this constitutes an additional basis for the VA’s denial decision in this case.

### CONCLUSION

For the foregoing reasons, this Court should quash the subpoenas and deny Defendants’ motion to compel.

Dated: September 11, 2017

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